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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,146	01/29/2002	Alexander Vainstein	10980-017001	1751

7590

06/07/2005

Fish & Richardson
225 Franklin Street
Boston, MA 02110-2804

EXAMINER

KOROMA, BARBA M

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	09/914,146		VAINSTEIN ET AL.	
	Examiner		Art Unit	
	Barba M. Koroma		1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 1-20,27 and 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-26 and 29-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 February 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Rejections of claims 25, 32, 29-39 based on 35 USC 112 Second paragraph; the rejection of claims 21, 23 and 26, based on 35 USC 102(b); the rejection of claims 21 and 23-26 under 35USC 102(b); rejection of claims 21-26 and 29-40 based on 35 USC 103(a), have been overcome by Applicant's arguments and claim amendments.
3. The objection to the Information Disclosure Statement is withdrawn due to Applicant amendments.
4. The objection to the specification is withdrawn in light of the amendment correcting the spelling error.

5. Priority

The amendment to first paragraph beginning page 1, line 1, of the specification is objected for containing new matter. The amendment states that the provisional application 60/121,239, filed on 2/22/1999, and PCT/1200/00110 are incorporated by reference in their entirety. See MPEP 608.01(P).

As a safeguard against the omission of a portion of a prior application for which priority is claimed under 35 U.S.C. 119(a)-(d) or (f), or for which benefit is claimed under 35 U.S.C. 119(e) or 120, applicant may include a statement at the time of filing of the later application incorporating by reference the prior application. See MPEP § 201.06(c) where domestic benefit is claimed. See MPEP § 201.13 where foreign priority is claimed. The inclusion of such an incorporation by reference statement in the later-filed application will permit applicant to include subject matter from the prior application into

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the later-filed application without the subject matter being considered as new matter. For the incorporation by reference to be effective as a proper safeguard, the incorporation by reference statement must be filed at the time of filing of the later-filed application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)).

6. Drawings

Applicants have submitted color photographs of Figures 3, 11, and 14. However, to be accepted, the submission must follow the requirements of 37 CFR 1.84.

7. *New Claim Rejections: 35 USC 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21, 22-25, and 29-40, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites "use of an oligonucleotide molecule." It is unclear how and what oligonucleotides should be used, or whether any and all oligonucleotides can be used. The metes and bounds of the claim are unclear. This rejection can be overcome by amending the claim to read: "by use of an antisense oligonucleotide targeting the fht gene".

Claim 21 recites "determining whether a change in fragrance has occurred." This recitation renders the claimed invention indefinite because it does not indicate that a change will occur. It is suggested the claim be reworded to recite "selecting plants with enhanced fragrance".

6. *Claim Rejections – 35 USC 112 First paragraph*

Enablement

Claims 21, and 29-40 remain and claims 22-26 are rejected under 35 USC 112, first paragraph, because the specification, while being enabling for a method of increasing fragrance of a plant comprising expressing an fht cDNA in antisense orientation in transgenic plants, it does not reasonably provide enablement for controlling fragrance in any other manner. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims, for the reasons of record stated in the Office Action mailed October 21, 2004. Applicant traversed the rejection in the paper filed February 22, 2005. The arguments were fully considered but not found persuasive.

Applicant argues on page 10, entire last paragraph of remarks, that the specification (page 8, lines 12-14) indicate that changing volatile molecules changes fragrance. Applicant also provides a declaration and 37CFR 1.132, signed by inventor Dr. Vainstain, which discusses that fragrance is a function of amounts of volatile compounds and the sensation of one who smells. Applicant argues further (remarks, page 11, last paragraph, beginning line 4), that the specification provides ample teachings about the anthocyanin pathway and its role in controlling the fragrance of a plant, adding that different combinations of metabolites produced by this pathway generate various fragrances. Thus, the arguments continue, one skilled in the art would recognize that he/she could control levels of metabolites in the pathway and thereby change fragrance.

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In the last sentence of page 11, Applicant concludes that the specification clearly teaches “specific role(s) and or mechanism(s) associated with the control of fragrance in carnation by anthocyanin-biosynthetic pathway gene(s).

However, the specification repeatedly teaches that fragrance is “enhanced” (page 33, line 9), is “more” (page 33, line 13), and is “higher” (page 33, line 15). Applicant’s discussion of what affects fragrance is noted. However, the working examples teach that fragrance is enhanced as a result of anti-sense suppression of fht. The specification at page 8, lines 12-14 state: Approach to olfactory enhancement of natural fragrance (emphasis added). In addition, the recitation “modulating gene expression” is not supported by the specification in that the term “modulation” encompasses both an upward and or downward expression of anthocyanin pathway-related genes, and end-products. Thus, if the genes were modulated such that anthocyanin biosynthetic pathway activities increase, the amounts of benzoic acid derivatives (fragrance compounds) would decrease simultaneously (see specification, page 8, lines 7-25). Applicant argues that genes encoding anthocyanin-biosynthesis pathway genes other than FHT can be used, that one can change levels of metabolites produced by the pathway by changing levels of metabolites produced by the pathway by changing enzyme levels (Applicant response, page 11, 2nd full paragraph). However, the specification teaches that it is the diversion of metabolic flow towards biosynthesis of benzoic acid derivatives, and inhibition of dihydroflavonal biosynthesis by fht antisense that causes the fragrance enhancement (paragraph bridging pages 33-34). Increasing gene expression of anthocyanin pathway genes would not cause this diversion. As indicated earlier, the specification only teaches

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anti-sense suppression of fht (see page 32, lines 18-24), and a concurrent increase in fragrant volatile levels in the transgenic plants (see specification, page 33, lines 12-19).

The specification does not teach all oligonucleotides and all methods of suing them, to decrease anthocynin biosynthesis pathway genes. Applicant argues that Dr. Vainstain's declaration point out that RNAi, and other techniques can be used. However, the specification does not discuss RNAi, or any other method of suppressing gene expression.

See Genentech, Inc. v. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Applicants also argue various in vivo and in vitro techniques are available for evaluating whether a factor regulates the expression of a gene (Applicant response, page 12, 4th full paragraph). However, the specification does not provide any guidance as to identity of those factors.

The enablement rejection is hereby maintained based on the broad recitation of claim 21²⁶, and dependent claims.

Conclusion

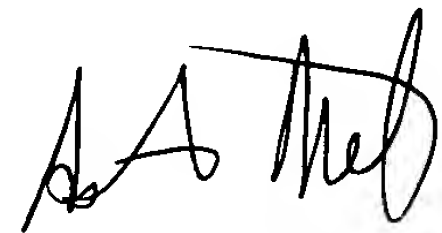
All prior art rejections have been overcome.

Contact Information

8. Any inquiry concerning this or earlier communications from the Examiner should be directed to Barba M. Koroma, whose telephone number is 571-272-0899. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at 571-272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are 571 273 8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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